

**Yorkshire & The Humber - Leeds East Research  
Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	Yorkshire & The Humber - Leeds East Research Ethics Committee
<b>Type of REC:</b>	Recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Establishing Research Tissue Banks, IRB Registered, Phase 1 Studies in Patients, Research Involving Children, Research Involving Adults Lacking Capacity
<b>Chair:</b>	Dr Rhona Bratt
<b>Vice-Chair:</b>	Dr Deborah Jane Fox
<b>Alternate Vice-Chair:</b>	Vacant
<b>REC Manager:</b>	Ms Katy Cassidy - August 2015 - ongoing Miss Christie Ord – July – August 2015 Ms Gillian Mayer – June 2015 Miss Sarah Grimshaw – April – May 2015
<b>REC Assistant:</b>	Miss Sarah Prothero August 2015 – ongoing Miss Kirstie Penman – July – August 2015 Miss Jade Robinson – June 2015
<b>Committee Address:</b>	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
<b>Telephone:</b>	020 7104 8081
<b>Email:</b>	nrescommittee.yorkandhumber-leedseast@nhs.net

## Chair's overview of the past year:

This is my second annual report as Chair of the Leeds (East) Research Ethics Committee. My thanks go to my vice-chair, Debbie Fox for her support in the past 12 months. This year we welcomed new member Nicolas Orsi to the committee. During this period two members left because of career and employment commitments Nader Touqan and Rebecca Forster. I would like to thank them for their services to the research ethics service. Their enthusiasm, knowledge and experience will be missed.

I should like to thank our new REC Manager, Katy Cassidy, for her work and also her colleagues who assisted us at various times during the year. We did have the good fortune to have just one REC assistant during the year, Sarah Prothero, and we are grateful for her experience and consistent work.

Research becomes ever more varied and complex and the committee members have attended many training courses to continue their professional development in Research Ethics review. The work of the committee took place in an environment of change within the Health Research Authority but the members' steadfast commitment to reviewing the research continued as always; calm, courteous and professional.

## Yorkshire & The Humber - Leeds East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Jennifer Blaikie	Senior Research Ethics Administrator	Lay Plus	01/01/2014	
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	01/08/2014	
Professor Kenneth Brodlie	Retired Professor of Visualization	Lay Plus	13/06/2011	
Dr Alexandros Chatziagorakis	ACF ST in General Adult Psychiatry	Expert	01/10/2014	
Ms Rebecca Forster	Project Specialist / Project Operations & Start-Up/ Clinical Development	Lay	01/10/2013	03/03/2016
Dr Deborah Jane Fox	Senior Lecturer in Nursing	Expert	01/04/2011	
Dr Stuart Jamieson	Consultant Neurologist	Expert	31/07/2007	01/05/2016
Mrs Ann Kay	Retired Special Needs Coordinator	Lay Plus	01/03/2014	
Dr Nicolas Orsi	Senior Research Fellow	Expert	01/12/2015	
Dr Andrew Pollard	Consultant Anaesthetist	Expert	22/09/2014	
Dr Anna Rees	Core medical trainee (year 2)	Expert	01/03/2014	
Mr Satti Saggi	Senior Associate for Research	Lay Plus	11/02/2015	
Mr Roly Squire	Consultant Paediatric Surgeon	Expert	31/07/2007	
Mr Nader Touqan	Speciality Training Registrar - Surgery	Expert	22/10/2013	31/10/2015
Mr Tom Wilson	Consultant ENT Surgeon	Expert	18/04/2011	
Miss Kate Woodrow	Assistant Chief Pharmacist	Expert	01/12/2012	

## Yorkshire & The Humber - Leeds East Research Ethics Committee: Deputy Members

None

## Yorkshire & The Humber - Leeds East Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Sheila E. Fisher	Retired Maxillofacial Surgeon/Clinical Research Fellow	Expert	07/04/2015 06/10/2015
Reverend Keith Lackenby	Superintendent Minister at Gainsborough Methodist Circuit	Lay Plus	Chaired the full meeting 02/06/2015 Chaired Ad Hoc SC 16/07/15

**Yorkshire & The Humber - Leeds East Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Miss Jennifer Blaikie	Employed by the University of Leeds, Jennifer looks after their internal ethical review process but is not directly involved in supporting University of Leeds researchers with their ethical applications.	10/02/2016
Dr Rhona Bratt	None declared	19/02/2016
Professor Kenneth Brodlie	None declared.	09/03/2016
Dr Alexandros Chatziagorakis	None declared.	12/02/2016
Ms Rebecca Forster	Rebecca previously performed research governance for Leeds community healthcare NHS trust. She also provided advice on applications prior to REC application and developed research ideas within the trust. Rebecca has since changed employment. "I assess the feasibility of and approve studies under the research governance framework for all research studies taking place in Leeds Community Healthcare Trust. I also provide support to staff in the development of research projects including the design, recruitment methodology, protocol and supporting information prior to REC submission."	12/02/2016
Dr Deborah Jane Fox	Deborah is a member of staff at Leeds Beckett University, where potential applicants may be a student or member of staff.	11/02/2016
Dr Stuart Jamieson	Founder share-holder in ClearSky medical diagnostics	16/02/2016
Mrs Ann Kay	None declared.	09/02/2016
Dr Nicolas Orsi	Consultant for Ostara Biomedical Ltd.Co-founder of Sleker LLC (USA).Trustee and co-founder of "Action on Womb Cancer."	25/11/2015
Dr Anna Rees	Anna is a core medical trainee at Wakefield Hospice.	29/02/2016
Mr Satti Saggi	Research Project Manager for the Academic Unit of Elderly Care and Rehabilitation at the Bradford Institute for Health Research. Community Champion for diabetes use.	18/02/2016
Mr Roly Squire	As part of his post as consultant paediatric surgeon at Leeds Teaching Hospitals NHS Trust, Roly will occasionally take part in discussions within the clinical team regarding potential research ideas, and will sometimes advise the clinicians involved regarding possible ethical considerations. He has no formal involvement in local or regional R&D. He is a surgical representative on the NCRI special study group for management of neuroblastoma, a paediatric tumour.	09/02/2016
Andrew Pollard	None declared	03/03/16
Tom Wilson	Clinician involved in research	03/03/16
Kate Woodrow	Local review of Clinical Trials Advisory Group applications from a pharmacy perspective. Future role in undertaking research as part of Doctorate of Pharmacy degree at the University of Bradford	03/03/16

### Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	07/04/2015	8
June	02/06/2015	9
July	07/07/2015	9
August	04/08/2015	11
September	01/09/2015	10
October	06/10/2015	8
November	03/11/2015	9
December	01/12/2015	12
February	02/02/2016	14
March	01/03/2016	10

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	23/04/2015	3
June	25/06/2015	3
July	23/07/2015	3
August	26/08/2015	3
October	02/10/2015	3
November	25/11/2015	3
December	16/12/2015	3
January	18/01/2016	3
February	15/02/2016	3
March	14/03/2016	3

10 proportionate review sub-committee meetings were held during the reporting period.

### Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	16/04/2015	2
April	30/04/2015	2
May	14/05/2015	2
May	27/05/2015	2
June	11/06/2015	2
June	25/06/2015	2
July	09/07/2015	2
July	16/07/2015	3
July	17/07/2015	2

July	21/07/2015	2
August	04/08/2015	2
August	20/08/2015	2
September	03/09/2015	2
September	15/09/2015	2
October	01/10/2015	2
October	12/10/2015	2
October	15/10/2015	2
October	29/10/2015	2
November	12/11/2015	2
November	26/11/2015	2
December	10/12/2015	2
December	21/12/2015	2
January	04/01/2016	2
January	11/01/2016	2
February	01/02/2016	2
February	15/02/2016	2
February	25/02/2016	2
February	29/02/2016	2
March	04/03/2016	2
March	07/03/2016	2
March	09/03/2016	2
March	11/03/2016	2
March	24/03/2016	3
March	28/03/2016	2

35 sub-committee meetings were held during the reporting period.

#### Details of inquorate meeting held: 01 April 2015 - 31 March 2016

None

**Attendance of Members at full committee meetings:01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Miss Jennifer Blaikie	5
Dr Rhona Bratt	9
Professor Kenneth Brodrie	7
Dr Alexandros Chatziagorakis	6
Ms Rebecca Forster	2
Dr Deborah Jane Fox	6
Dr Stuart Jamieson	9
Mrs Ann Kay	7
Dr Nicolas Orsi	2
Dr Andrew Pollard	6
Dr Anna Rees	9
Mr Satti Saggi	6
Mr Roly Squire	7
Mr Nader Touqan	4
Mr Tom Wilson	6
Miss Kate Woodrow	6

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Miss Jennifer Blaikie	1
Dr Rhona Bratt	8
Professor Kenneth Brodrie	1
Dr Alexandros Chatziagorakis	2
Dr Deborah Jane Fox	4
Dr Stuart Jamieson	3
Mrs Ann Kay	4
Dr Andrew Pollard	1
Dr Anna Rees	2
Mr Satti Saggi	1
Mr Roly Squire	2
Mr Tom Wilson	1

**Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Miss Jennifer Blaikie	3
Dr Rhona Bratt	27
Professor Kenneth Brodrie	3



Dr Alexandros Chatziagorakis	4
Dr Deborah Jane Fox	9
Dr Stuart Jamieson	2
Mrs Ann Kay	5
Dr Andrew Pollard	2
Dr Anna Rees	3
Mr Satti Saggu	3
Mr Roly Squire	6
Mr Nader Touqan	1
Mr Tom Wilson	2
Miss Kate Woodrow	1

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Miss Jennifer Blaikie	15/10/2015	Training - Assessing the Consequences (benefits and harms) of Research
Miss Jennifer Blaikie	14/05/2015	Good Practice in Research Ethics
Miss Jennifer Blaikie	03/07/2015	Research Ethics Study Day
Miss Jennifer Blaikie	15/10/2015	Training - Assessing the Consequences (benefits and harms) of Research
Miss Jennifer Blaikie	16/10/2015	NREAP Hosted Meeting
Miss Jennifer Blaikie	01/11/2015	e-Learning, Improving Healthcare Through Clinical Research
Miss Jennifer Blaikie	21/11/2015	e-Learning Course, Children and Clinical Research
Miss Jennifer Blaikie	03/02/2016	Self-Directed Learning Log
Dr Rhona Bratt	06/05/2015	NREAP Hosted Meeting
Dr Rhona Bratt	16/10/2015	NREAP Hosted Meeting
Dr Rhona Bratt	29/06/2015	Researcher Training Day
Dr Rhona Bratt	03/07/2015	Researcher Training Day at University of Leeds
Dr Rhona Bratt	12/11/2015	Researcher Training Day
Dr Rhona Bratt	21/11/2015	e-Learning Course, Children and Clinical Research
Dr Rhona Bratt	01/11/2015	e-Learning, Improving Healthcare Through Clinical Research
Dr Rhona Bratt	09/12/2015	National Training Day for Committee Chairs
Dr Rhona Bratt	04/02/2016	Researcher Training Day
Dr Rhona Bratt	20/04/2016	Researcher Training Day
Dr Rhona Bratt	16/03/2016	Training - National Members Training Day
Dr Rhona Bratt	22/03/2016	Self-Directed Learning Log
Professor Kenneth Brodlie	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Alexandros Chatziagorakis	13/04/2015	Equality and Diversity Training
Ms Rebecca Forster	08/06/2015	Equality and Diversity - Appreciating Differences
Dr Deborah Jane Fox	09/12/2015	National Training Day for Committee Chairs
Mrs Ann Kay	04/06/2015	Local Training Day
Dr Nicolas Orsi	16/03/2016	Training - National Members Training Day
Dr Andrew Pollard	04/06/2015	Local Training Day
Dr Andrew Pollard	17/06/2015	Training - NRES Committee Members Induction
Dr Anna Rees	06/03/2016	Adults Lacking Capacity to Consent to Research
Dr Anna Rees	08/03/2016	Read the effect of consent

		rituals on mortality in emergency care research
Dr Anna Rees	08/03/2016	Read the guide to the design and review of emergency research when it is proposed that consent and consultation be waived
Dr Anna Rees	12/03/2016	Read Adults Lacking Capacity in CTIMPs
Mr Satti Saggu	04/06/2015	Local Training Day
Mr Satti Saggu	24/09/2015	Training - NRES Committee Members Induction
Miss Kate Woodrow	04/06/2015	Local Training Day - York
Miss Kate Woodrow	16/03/2016	Training - National Members Training

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	25	43.86
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	3.51
Research Database (including renewals)	0	0.00
Others	30	52.63
<b>Total Applications Reviewed</b>	<b>57</b>	<b>100</b>

**Table 2: Breakdown of full applications and other activity during reporting period**

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	15
Number of paediatric applications reviewed	7
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	6
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	2

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	5.26
Favourable Opinion with Additional Conditions	5	8.77
Unfavourable Opinion	1	1.75
Provisional Opinion	48	84.21
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>57</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

**Table 4: Summary of current status of applications reviewed during the reporting period**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	44	77.19
Further Information Favourable Opinion with Additional Conditions	4	7.02
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.26
Favourable Opinion with Additional Conditions	5	8.77
Unfavourable Opinion	1	1.75
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>57</b>	<b>100</b>

**Table 5: Applications assigned to a proportionate review sub-committee within the reporting period**

<b>Total Applications Reviewed</b>	<b>31</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	18
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	10

**Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	23	74.19
Favourable Opinion with Additional Conditions	1	3.23
No Opinion transfer to full committee for review	3	9.68
Provisional Opinion	4	12.90
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>31</b>	<b>100</b>

**Table 8: Other Management Information based on the number of completed applications for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.70
<b>Number of completed applications for full ethical review</b>	57
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	4
<b>Number of completed applications over 40 days as a % of total</b>	7.02%
<b>Number of days taken to final decision – average (mean)</b>	28
<b>Number of completed proportionate review applications for ethical review</b>	28
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	23
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	150
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	4
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	2.67%
<b>Number of modified amendments reviewed</b>	1
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of minor amendments received</b>	103
<b>Number of substantial amendments received for information</b>	4
<b>Number of substantial amendments received for new sites/PIs</b>	57
<b>Number of annual progress reports received</b>	77
<b>Number of safety reports received</b>	53
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	17





**Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/YH/0125	Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001	17
15/YH/0127	A8241022 - PF-02545920 IN SUBJECTS WITH HUNTINGTON'S DISEASE	53
15/YH/0129	Proactive Telephone Coaching & Tailored Support (PROTECTS)	34
15/YH/0134	The "R-3D-2" pilot study.	22
15/YH/0235	IMPACCT	25
15/YH/0237	Survival and Quality of life of Cancer Patients with incidental PE	25
15/YH/0239	Comparison of dupilumab to dummy drug when added to asthma treatment	35
15/YH/0252	POD study	35
15/YH/0295	STEADY study	25
15/YH/0306	Exercise intolerance in CHF following CRT (V1)	26
15/YH/0316	REO13 Melanoma GMCSF	22
15/YH/0325	CFOR258D2416 - A study of an inhaled corticosteroid In pts with asthma	22
15/YH/0337	Improving care pathways for frequent users of emergency care	23
15/YH/0343	Accelerating Delivery Of Psychological Therapies after Stroke (ADOPTS)	23
15/YH/0345	A comparison of patient choice of termination of pregnancy procedures	24
15/YH/0368	232SM202 - Spinal Muscular Atrophy	26
15/YH/0370	Surgical Wounds Healing by Secondary Intention - SWHSI	28
15/YH/0374	Can axillary surgery be tailored dependent on response to chemotherapy	27
15/YH/0378	Organ Care System (OCS <sup>®</sup> ) Liver 'REVIVE' Trial	22
15/YH/0388	Ceritinib food effect study in ALK positive NSCLC patients	22
15/YH/0407	Single Dose of MK-0517 for Prevention of CINV in Paediatric Subjects	24
15/YH/0412	Diversion Colitis	29
15/YH/0413	Fitabisc	32
15/YH/0428	4228: DUAL <sup>®</sup> VIII – Durability, IDegLira vs IGlax in Type 2 diabetes	25
15/YH/0434	Idelalisib Dose Optimisation Study	25
15/YH/0484	I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis	22
15/YH/0485	GP15-301 Study to compare GP2015 and Enbrel <sup>®</sup> in Rheumatoid Arthritis	22
15/YH/0489	REVAKI-2	32
15/YH/0491	MEASURING PROGRESS IN LABOUR WITHOUT THE USE OF VAGINAL EXAMINATION	36
15/YH/0529	Psychological outcomes of eye conditions & treatment in childhood.	28
15/YH/0530	CLARITY	25
15/YH/0532	Objective measures of visual improvement following amblyopia therapy	26

15/YH/0534	fMRI and PET-CT in Idiopathic Pulmonary Fibrosis	28
15/YH/0535	TRANSITION_LCZ696 pre/ post discharge in acute heart failure	29
16/YH/0013	Immune Factors in Neurological Diseases v1	58
16/YH/0020	A Study of INC280 (Alone or in Combination) in Patients with NSCLC	29
16/YH/0024	233AS101 - Phase 1 Study in ALS	30
16/YH/0025	Assessment in Leeds of Biomarkers Early after Renal Transplantation	33
16/YH/0026	A clinical outcome assessment for Wolf-Hirschhorn syndrome	27
16/YH/0032	Rituximab Objective Outcome measures Trial in SLE (ROOTS)	27
16/YH/0068	A longer-term care strategy for stroke – a feasibility study	43
16/YH/0081	TULIP-LN1	27
16/YH/0083	PEGPH20 in patients with pancreatic cancer with high levels of HA	36
16/YH/0084	Efficacy and Safety of rexlemestrol-L in Chronic Heart Failure	27

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0294	Pro-Euro-DILI Registry version 1	29
15/YH/0309	Type-2 Diabetes; Adults with inadequate glycaemic control on Metformin	34
15/YH/0346	Physical Functional Abilities in Adults with Cerebral Palsy	23
15/YH/0490	MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA	24

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0099	Leeds NIHR Biomarker Research Tissue Bank	50
15/YH/0310	MB29599 - A Study to Assess Biomarkers in Patients with Severe Asthma	23
15/YH/0311	UCL/UCLH Biobank for Studying Health and Disease	27

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0144	Exploring Context Change Study	29

15/YH/0233	ClearCarotid	23
15/YH/0486	influenza-specific nasal IgA	21
16/YH/0077	Chemoprevention with Tamoxifen or Raloxifene	24
16/YH/0078	Detecting transitional cell carcinoma from haematuria	24

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/YH/0424	Exploration of the use of seclusion in an Acute Unit and a PICU	24

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/YH/0209	Adherence to self-management regimes in type 2 diabetes	11
15/YH/0212	RCT - Rehab for plantar fasciitis (hamstring stretches)	12
15/YH/0358	Backpack v1	9
15/YH/0445	Exploring the role of thoughts in adult patients with tinnitus (1)	12

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0210	Inflammatory Bowel Disease environmental factors and outcomes.	11
15/YH/0211	(duplicate) Understanding patient recruitment into Surgical Clinical Trials	11
15/YH/0304	Burns Wound Dressing Volatile Compounds - follow on study (DRESSVOCS2)	11
15/YH/0305	Does an abnormal UAPI follow a predictable change over time	10
15/YH/0308	Dental pulp cells for auditory and peripheral nerve regeneration	11
15/YH/0356	Goal facilitation in rehabilitation after stroke	12
15/YH/0359	RESPECT-21: evaluation of specialist cancer surgery reorganisation	8
15/YH/0408	Longitudinal Trajectories of Child Growth in Manchester (Phase 2)	11
15/YH/0541	Cardiovascular Acoustics - Version 1	14
15/YH/0544	Social media use in patients and relatives	14
15/YH/0545	Public and clinicians' views of Prudent Healthcare	13
15/YH/0570	Patient preparation effect on prostate and bladder MRI	7
15/YH/0571	Epstein-Barr virus and Transformation of Follicular Lymphoma	8
16/YH/0027	Analysis of 123I FP-CIT SPECT Image Characteristics	10
16/YH/0029	Experience of caring for a child with an implanted loop record Ver1	12
16/YH/0034	Identification of medical students in the clinical setting	9
16/YH/0070	Developing a cognitive intervention: A two-stage focus group	7
16/YH/0071	Does hand grip strength change over a haemodialysis session?	7
16/YH/0072	Comparison of ADR reports received via Yellow Card app with case notes	7
16/YH/0117	Role of metastatic markers in breast cancer	10
16/YH/0118	Characterisation of monocyte CD200R in pulmonary sarcoidosis (v 1.0)	14
16/YH/0121	Carers' Experiences of Unusual Beliefs	13
16/YH/0122	People's experiences of self-managing COPD after hospital discharge	13

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/YH/0406	Self-efficacy in early physical trauma patients	9

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
03/193 LE/AM04	Circulating Haemostatic etc in pathogeneis of dementia	Substantial Amendment 19, 02/1	13/10/2015	20
05/Q1206/147/AM01	THE LEEDS 10K PROJECT	Substantial Amendment 1 - March 2015	02/03/2015	8
05/Q1206/168/AM40	PATCH, Version 1.0	Substantial Amendment 27, 18/0	18/08/2015	14
07/H1306/127/AM08	TRISST, version 1.0	Substantial Amendment 7	19/05/2015	14
07/Q1206/47/AM02	BLIMP1 related transcription factor network in health and disease 1	Substantial Amendment 1	17/07/2015	12
07/Q1206/53/AM30	Imatinib versus nilotinib in newly diagnosed Ph+ve CML	Protocol Amendment 10	01/04/2015	26
08/H1306/147+5/AM01	Respiratory Tissue Bank	Substantial Amendment 1	28/07/2015	7
08/H1306/147+5/AM02	Respiratory Tissue Bank	Substantial Amendment 2, 16/10	19/10/2015	14
09/H1306/109/AM07	Arterial Elasticity: A Substudy of START	Substantial Amendment 6, 02/10	14/10/2015	17
09/H1306/119/AM08	Timing of Primary Surgery for Cleft Palate (TOPS) v1.1	Substantial Amendment 3, 26/08	09/09/2015	22
09/H1306/54/AM22	ARCTIC (FCR Vs FCM-miniR) Version 1.0	Substantial Amendment 19	03/08/2015	16
09/H1306/64/AM38	Strategic Timing of AntiRetroviral Treatment (START)	Substantial Protocol Amendment	12/02/2016	10
09/H1306/65/AM13	A long-term Registry of Pediatric Patients with Crohn's Disease	Substantial	26/11/2015	14

		Amendment 3, 22/06		
09/H1306/97/AM13	South Yorkshire Cohort	Substantial Amendment 11	17/03/2015	17
09/H1306/97/AM14	South Yorkshire Cohort	Substantial Amendment 12, 01/0	18/02/2016	11
10/H1306/40/AM02	Effects of intravenous iron therapy on markers of acute kidney injury	Substantial Amendment 2, 18/06/15	18/06/15	21
10/H1306/42/AM06	UCL-Cancer Institute and Pathology Biobank	Substantial Amendment 6	27/03/2015	21
10/H1306/82/AM03	Novel Calcium Channels in Primary and Secondary Liver Tumours - Ver 1	Substantial Amendment 3 - 04/06/2015	01/06/2015	17
11/H1306/1/AM16	CC-10004-PSA-005 Apremilast in Active Psoriatic Arthritis	Updated IB v15 - 16/03/2015	16/03/2015	16
11/YH/0036/AM01	Empowering adolescent patients in undergraduate education	Substantial Amendment 1	27/05/2015	8
11/YH/0145/AM07	Study of Recombinant Factor IX Product, IB1001, in Previously Treated	Protocol IB1001-02 Amendment dated 07 April 2015, IB 1001 IB Version 8.0 dated April 2015, IB1001 IMPD version 7.1 dated 23 January 2014	30/04/2015	15
11/YH/0145/AM08	Study of Recombinant Factor IX Product, IB1001, in Previously Treated	Substantial Amendment 6, 12/11	12/11/2015	8
11/YH/0290/AM08	STOMP: SCLC Trial of Olaparib (AZD2281) as Maintenance Programme.	Substantial Amendment 6, 03/09	07/09/2015	14
11/YH/0363/AM02	ELSSI	Substantial Amendment 1	06/05/2015	7
11/YH/0363/AM03	ELSSI	Substantial Amendment 2,	11/12/2015	3

		11/12		
11/YH/0373/AM11	A study of selumetinib in patients with Kaposi's sarcoma	Substantial Amendment 10, 01/0	28/09/2015	17
11/YH/0373/AM12	A study of selumetinib in patients with Kaposi's sarcoma	Substantial Amendment 11, 01/1	14/12/2015	6
12/YH/0179/AM24	0117 - Phase 3 Extension Study of GS-1101 in CLL	Substantial Amendment – IB 13	03/12/2015	9
12/YH/0298/AM07	ELCASA_v1.2	Substantial Amendment 7	31/03/2015	16
12/YH/0318/AM19	0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL	Substantial Amendment - IB 13	16/12/2015	6
12/YH/0318/AM21	0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL	Substantial Amendment 6, 15/12	05/02/2016	10
12/YH/0328/AM05	Procoagulant mechanisms of chemotherapy in multiple myeloma	Substantial Amendment 3, 15/02	16/02/2016	12
12/YH/0343/AM06	CF Trust Funded 3Helium MRI MBW	Substantial Amendment 4	13/04/2015	28
12/YH/0401/AM14	RAY- PCI32765MCL3001	Substantial Amendment 7, 04/08	30/09/2015	10
12/YH/0401/AM15	RAY- PCI32765MCL3001	Substantial Amendment 8, 08/12	08/12/2015	13
12/YH/0446/AM14	Sirukumab in Participants with Active RA Despite Anti-TNF Therapy	Amendment 10	05/03/2015	20
12/YH/0446/AM16	Sirukumab in Participants with Active RA Despite Anti-TNF Therapy	Substantial Amendment 12	30/03/2015	20
12/YH/0446/AM17	Sirukumab in Participants with Active RA Despite Anti-TNF Therapy	Substantial Amendment updated IB ed 10 - 27/04/2015	27/04/2015	15
12/YH/0446/AM21	Sirukumab in Participants with Active RA Despite Anti-TNF	Substantial	23/11/2015	10



	Therapy	Amendment 14, 23/1		
12/YH/0446/AM22	Sirukumab in Participants with Active RA Despite Anti-TNF Therapy	Substantial Amendment 15, 04/0	04/01/2016	8
12/YH/0452/AM39	INCA	Substantial Amendment 33, 27/0	27/01/2016	19
12/YH/0475/AM07	GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA	Substantial Amendment 4	18/05/2015	8
12/YH/0475/AM08	GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA	Updated Investigators Brochure	19/06/2015	14
12/YH/0475/AM10	GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA	Substantial Amendment 6, 08/12	08/12/2015	12
12/YH/0488/AM04	Regenerative Endodontic Technique for management of immature teeth V1	Substantial Amendment 3, 16/09	05/11/2015	7
12/YH/0498/AM18	MTL-005 Radiosensitization in patients with head & neck cancer	Substantial Amendment 12, 28/0	28/08/2015	16
13/YH/0011/AM10	Open label study of PCI-32765 vs Chlorambucil in CLL/SLL	Substantial amendment 8	17/02/2015	15
13/YH/0012/AM13	Open label extension study of PCI-32765 in CLL/SLL	Substantial Amendment 8, 09/03	09/03/2016	16
13/YH/0098/AM01	Mechanisms and Reversibility of Heart Failure associated with Diabetes	Amendment 2	21/05/2015	28
13/YH/0126/AM09	GWCA1208 - Study of Sativex in Patients with Recurrent Glioblastoma	Substantial Amendment 2	21/04/2015	20
13/YH/0126/AM10	GWCA1208 - Study of Sativex in Patients with Recurrent Glioblastoma	Substantial Amendment 6 - 21/05/2015	21/05/2015	31
13/YH/0126/AM12	GWCA1208 - Study of Sativex in Patients with Recurrent Glioblastoma	Substantial Amendment 7, 31/12	18/01/2016	21

13/YH/0229/AM10	GO2, Version 1.0	Substantial Amendment 8	17/03/2015	18
13/YH/0252/AM12	Travellers and Vaccinations	Substantial amendment 8 - 10/06/2015	10/06/16	16
13/YH/0281/AM04	Evaluation of [18F]-FET- <sup>125</sup> I-AG-TOCA for the imaging of NETs	Substantial Amendment 2	16/04/2015	14
13/YH/0282/AM15	ML28641 - Subcutaneous tocilizumab in rheumatoid arthritis	Substantial Amendment 9, 01/03	01/03/2016	8
13/YH/0313/AM18	BAY 85-3934 for the treatment of anaemia associated with CKD v placebo	Substantial Amendment 10	14/05/2015	13
13/YH/0314/AM10	Extension study of BAY 85-3934 in the long-term treatment of anaemia	Substantial Amendment 7	14/05/2015	13
13/YH/0314/AM12	Extension study of BAY 85-3934 in the long-term treatment of anaemia	Substantial Amendment 8, 27/01	27/01/2016	19
13/YH/0315/AM15	BAY85-3934 for treatment of anaemia associated with CKD v darbepoetin	Substantial Amendment 7	14/05/2015	13
13/YH/0333/AM08	Long term study for participants completing SIRROUND-D and SIRROUND-T	Substantial Amendment 8, 13/03	13/03/2015	20
13/YH/0333/AM09	Long term study for participants completing SIRROUND-D and SIRROUND-T	Substantial Amendment 8	30/03/2015	20
13/YH/0333/AM10	Long term study for participants completing SIRROUND-D and SIRROUND-T	Substantial Amendment IB Ed 10 - 27/04/2015	27/04/2015	15
13/YH/0333/AM14	Long term study for participants completing SIRROUND-D and SIRROUND-T	Substantial Amendment 11, 23/1	23/11/2015	10
13/YH/0333/AM15	Long term study for participants completing SIRROUND-D and SIRROUND-T	Substantial Amendment 12, 04/0	04/01/2016	8
13/YH/0346/AM05	Sildenafil in Heart Failure	Substantial Amendment 4, 18/08	22/09/2015	17
13/YH/0388/AM01	Chlorhexidine Against Povidone-Iodine Trial (CAPIT)	Substantial	02/07/2015	7

		Amendment 1		
14/YH/0058/AM05	FIDELITY	Substantial Amendment 4, 16/08	14/08/2015	14
14/YH/0088/AM03	Phase I study of KHK2823 in AML or MDS	Substantial Amendment 3	12/06/2015	19
14/YH/0090/AM04	Study to test ADIPEG20 in patients with mesothelioma and NSCLC V 02	Substantial Amendment 4 - 22/05/2015	22/05/2015	12
14/YH/0092/AM07	Reduced-dosed rivaroxaban in the long-term prevention of VTE	Substantial Amendment 5, 30/10	22/12/2015	13
14/YH/0123/AM03	1325 - Expanded access study with Idelalisib in patients with CLL	Substantial Amendment 3	18/03/2015	20
14/YH/0123/AM04	1325 - Expanded access study with Idelalisib in patients with CLL	Substantial Amendment - 4 29 12 2015	18/12/2015	6
14/YH/0131/AM05	ACP-196 in Subjects with Chronic Lymphocytic Leukemia	Substantial Amendment 4	22/06/2015	18
14/YH/0131/AM07	ACP-196 in Subjects with Chronic Lymphocytic Leukemia	Substantial Amendment 5, 01/12	01/12/2015	12
14/YH/0131/AM09	ACP-196 in Subjects with Chronic Lymphocytic Leukemia	Substantial Amendment 6, 09/02	09/02/2016	20
14/YH/0178/AM01	Non invasive transcutaneous vagus nerve stimulation in heart failure	Substantial Amendment 1, 08/12	15/12/2015	13
14/YH/0181/AM06	REPORT-UK: Phase 3 Pilot study (Version 1)	Substantial Amendment 2	27/05/2015	15
14/YH/1052/AM04	The MUNROS project: the questionnaires (Work Packages 4,5 and 6)	Amendment 3, 12/03/15	12/03/2015	34
14/YH/1052/AM10	The MUNROS project: the questionnaires (Work Packages 4,5 and 6)	Substantial Amendment 4, 15/10	28/10/2015	14
14/YH/1052/AM11	The MUNROS project: the questionnaires (Work Packages 4,5 and 6)	Substantial Amendment 5,	19/01/2016	13

		18/12		
14/YH/1052/AM12	The MUNROS project: the questionnaires (Work Packages 4,5 and 6)	Substantial Amendment 6, 14/3/	21/03/2016	9
14/YH/1056/AM02	Phase2/3 of masitinib+dexamethasone & gemcitabine in TCell lymphoma v1	Substantial Amendment 2	14/05/2015	25
14/YH/1056/AM04	Phase2/3 of masitinib+dexamethasone & gemcitabine in TCell lymphoma v1	Substantial Amendment 4, 21/09	09/10/2015	20
14/YH/1056/AM06	Phase2/3 of masitinib+dexamethasone & gemcitabine in TCell lymphoma v1	Substantial Amendment 6, 29/12/2015	07/12/2015	7
14/YH/1057/AM05	Sofosbuvir/GS-5816 v. Sofosbuvir and Ribavirin in HCV	Substantial Amendment 3	20/03/2015	22
14/YH/1057/AM07	Sofosbuvir/GS-5816 v. Sofosbuvir and Ribavirin in HCV	Substantial Amendment 4	12/06/2015	19
14/YH/1066/AM02	eRAPID RCT in systemic cancer treatment	Substantial Amendment 1.3 - 11/05/2015	11/05/2015	14
14/YH/1082/AM01	Intralipid and IVF Study	Substantial Amendment version 2 - 02/03/2015	02/03/2015	15
14/YH/1084/AM04	Cadazolid /ACT-179811 Clostridium Difficile associated diarrhoea(CDAD)	Substantial Amendment 3	14/05/2015	13
14/YH/1090/AM11	QUIET-1: The Quest in Eliminating Tinnitus	Substantial Amendment 5, 09/10	12/10/2015	0
14/YH/1097/AM01	Development of Tests to Measure Medicines in the Body	Substantial Amendment 1	15/06/2015	11
14/YH/1101/AM01	Accelerated version 1.0	Substantial Amendment 1, 15/06	10/08/2015	28
14/YH/1112/AM05	A8241021 - PF-02545920 IN SUBJECTS WITH HUNTINGTON'S DISEASE	Amendment 6 - 02/04/2015	02/04/2015	15
14/YH/1112/AM06	A8241021 - PF-02545920 IN SUBJECTS WITH HUNTINGTON'S DISEASE	Substantial Amendment 5	18/03/2015	9

14/YH/1112/AM07	A8241021 - PF-02545920 IN SUBJECTS WITH HUNTINGTON'S DISEASE	Substantial Amendment 7	08/04/2015	8
14/YH/1125/AM01	Vitamin D & PCOS	Substantial Amendment 1, 02/09	09/09/2015	13
14/YH/1138/AM01	Exercise for falls prevention in lower limb amputees_V1	Substantial amendment 1	20/02/2015	20
14/YH/1147/AM03	Steroids and their impact on your muscles and physical activity	Amendment 3	19/01/2015	16
14/YH/1147/AM04	Steroids and their impact on your muscles and physical activity	Substantial Amendment 4, 20/08	18/08/2015	17
14/YH/1147/AM05	Steroids and their impact on your muscles and physical activity	Substantial Amendment 5, 15/12	17/12/2015	4
14/YH/1153/AM05	Open-label extension study of LMTM in Alzheimers & bvFTD patients	Substantial Amendment 2 - IB v1	20/02/2015	21
14/YH/1153/AM09	Open-label extension study of LMTM in Alzheimers & bvFTD patients	Substantial Protocol Amendment 1.1, 11/06/14	09/12/2015	14
14/YH/1199/AM07	GALACTIC version 1.0	Substantial Amendment 7, 16/12	04/01/2016	6
14/YH/1204/AM03	Phase2 Gilead Study Safety&Efficacy of Idela&Rituximab in CLL patients	Substantial Amendment 3, IB Ed	11/12/2015	8
14/YH/1282/AM02	PF-06252616 in Boys with Duchenne Muscular Dystrophy	Substantial Amendment 2	22/05/2015	25
14/YH/1282/AM03	PF-06252616 in Boys with Duchenne Muscular Dystrophy	Substantial Amendment 3 - 18/0	18/05/2015	17
14/YH/1293/AM02	Acute recreational drug toxicity in the Emergency Department	Substantial amendment 1	30/03/2015	26
14/YH/1293/AM03	Acute recreational drug toxicity in the Emergency Department	Substantial Amendment 2, 04/02	24/02/2016	9

15/YH/0009/AM02	Pinsite Infection In Circular Frames - PINS trial	Substantial Amendment 1	16/05/2015	16
15/YH/0019/AM01	A study of SAR113244 treatment in patients with lupus.	Substantial Amendment 1 - 27/05/2015	01/06/2015	30
15/YH/0051/AM01	SCIMITAR Plus (version 1.0)	Major Amendment 2	02/06/2015	24
15/YH/0051/AM02	SCIMITAR Plus (version 1.0)	Substantial Amendment 3 - 26/06/2015	29/06/2015	11
15/YH/0051/AM05	SCIMITAR Plus (version 1.0)	Substantial Amendment 5, 21/07	28/07/2015	20
15/YH/0051/AM09	SCIMITAR Plus (version 1.0)	Substantial Amendment 9, 25/09	01/10/2015	14
15/YH/0051/AM13	SCIMITAR Plus (version 1.0)	Substantial Amendment 13, 04/0	04/02/2016	14
15/YH/0051/AM14	SCIMITAR Plus (version 1.0)	Substantial Amendment 14, 17/0	18/02/2016	11
15/YH/0051/AM15	SCIMITAR Plus (version 1.0)	Substantial Amendment 15, 10/0	11/03/2016	25
15/YH/0094/AM01	The impact of nutrition risk status on older people in the community	Substantial Amendment 1	17/05/2015	21
15/YH/0094/AM02	The impact of nutrition risk status on older people in the community	Substantial Amendment 2, 26/01	27/01/2016	21
15/YH/0125/AM01	Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001	Substantial Amendment 1	13/05/2015	14
15/YH/0125/AM04	Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001	Substantial Amendment 3	22/06/2015	18
15/YH/0129/AM02	Proactive Telephone Coaching & Tailored Support (PROTECTS)	Substantial Amendment 1	01/07/2015	15
15/YH/0129/AM07	Proactive Telephone Coaching & Tailored Support	Substantial	12/01/2016	19

	(PROTECTS)	Amendment 2, 05/01		
15/YH/0136/AM01	MISSION	Substantial Amendment 1, 14/10	23/10/2015	17
15/YH/0143/AM01	Exploring decision-making following attendance at unscheduled care	Substantial Amendment 1, 12/01	14/01/2016	11
15/YH/0209/AM01	Adherence to self-management regimes in type 2 diabetes	Substantial Amendment 1, 01/09	01/09/2015	13
15/YH/0212/AM01	RCT - Rehab for plantar fasciitis (hamstring stretches)	Substantial Amendment 1, 05/01	04/01/2016	7
15/YH/0235/AM01	IMPACCT	Substantial Amendment 1, 18/12	22/12/2015	13
15/YH/0235/AM02	IMPACCT	Substantial Amendment 2, 03/03	08/03/2016	22
15/YH/0237/AM01	Survival and Quality of life of Cancer Patients with incidental PE	Substantial Amendment 1, 03/11	05/11/2015	7
15/YH/0239/AM01	Comparison of dupilumab to dummy drug when added to asthma treatment	Substantial Amendment 1	03/08/2015	16
15/YH/0239/AM02	Comparison of dupilumab to dummy drug when added to asthma treatment	Substantial Amendment 2, 09/10	09/10/2015	21
15/YH/0239/AM03	Comparison of dupilumab to dummy drug when added to asthma treatment	Substantial Amendment 3, 03/11	03/11/2015	9
15/YH/0252/AM01	POD study	Substantial Amendment 1, 08/01	18/01/2016	7
15/YH/0294/AM01	Pro-Euro-DILI Registry version 1	Substantial Amendment 1, 25/01	26/01/2016	23

15/YH/0295/AM02	STEADY study	Substantial Amendment 2, 01/09	24/11/2015	15
15/YH/0304/AM01	Burns Wound Dressing Volatile Compounds - follow on study (DRESSVOCS2)	Substantial Amendment 1, 22/10	26/10/2015	7
15/YH/0306/AM01	Exercise intolerance in CHF following CRT (V1)	Substantial Amendment 1, 26/10	02/11/2015	9
15/YH/0309/AM01	Type-2 Diabetes; Adults with inadequate glycemc control on Metformin	Substantial Amendment 1, 02/12	02/12/2015	8
15/YH/0309/AM05	Type-2 Diabetes; Adults with inadequate glycemc control on Metformin	Substantial Amendment 2, 16/02	16/02/2016	10
15/YH/0310/AM01	MB29599 - A Study to Assess Biomarkers in Patients with Severe Asthma	Substantial Amendment 1, 24/08	27/08/2015	6
15/YH/0337/AM01	Improving care pathways for frequent users of emergency care	Substantial Amendment 1, 17/09	30/09/2015	15
15/YH/0343/AM02	Accelerating Delivery Of Psychological Therapies after Stroke (ADOPTS)	Substantial Amendment 1, 18/12	23/12/2015	9
15/YH/0434/AM03	Idelalisib Dose Optimisation Study	Substantial Amendment 2 - 25/11/2015	25/11/2015	15
15/YH/0484/AM01	I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis	Substantial Amendment 1, 13/01	18/01/2016	14
15/YH/0490/AM01	MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA	Substantial Amendment 1, 14/12	08/12/2015	7
15/YH/0530/AM01	CLARITY	Substantial Amendment 1, 13/02	05/02/2016	10
16/YH/0072/AM01	Comparison of ADR reports received via Yellow Card app with	Substantial	08/03/2016	9



	casenotes	Amendment 1, 03/02		
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<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/YH/0131/AM04	ACP-196 in Subjects with Chronic Lymphocytic Leukemia	Substantial Amendment 3	15/06/2015	35

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/YH/0131/AM04/1	ACP-196 in Subjects with Chronic Lymphocytic Leukemia	Modified Substantial Amendment	13/08/2015	8

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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